



American Remedies Healthcare Pvt. Ltd.

Surajpur, Nahan Road Paonta sahib Dist. Sirmour (H.P)

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF FINISHED PRODUCT ANALYSIS

Product Name:	Sensodex Heavy (Bupivacaine HCL in Dextrose Injection USP-4 ml)		
Batch No.	26AR089	A.R. No.	AFP260101
Batch Size	100000 Vials	Sample Quantity	60 Nos
Mfg. Date	08/2026	Date of Testing	23/08/2026
Exp. Date	07/2028	Date of Release	07/09/2026
Reference Batch No	26AR089	MFG. Lic. No.	HP-MB-LL-00235

Sr. No.	Test	Specification	Observation
1.	Description	A clear colorless liquid solution	A clear colorless liquid solution
2.	Identification A) (By TLC) B) (By HPLC)	The R _F value of the Bupivacaine spot obtained from the test preparation corresponds to those obtained from the adjacent chromatogram of the standard preparation A and C. The retention time of the Bupivacaine peak in the Sample solution correspond to the sample solution Corresponds to that of the standard solution , as obtained in the assay	Complies Complies
3.	pH	Between 4.0 to 6.5	6.14
4.	Extractable Volume	NLT 4.0ml	4.0ml
5.	Particulate Matter (Visible Particles)	Injections that are solutions, when examined under suitable conditions of visibility, are clear and practically free from particles that can be observed on visual inspection by the unaided eye.	Complies



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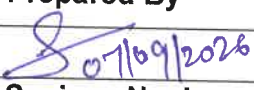
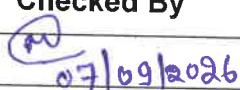
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	(Sub Visible Particles) Particles of $\geq 10 \mu\text{m}$ Particles of $\geq 25 \mu\text{m}$	NMT 6000 particles of $10 \mu\text{m}$ NMT 600 particles of $25 \mu\text{m}$	Complies Complies
6.	Bacterial Endotoxins	Not more than 1.8 USP EU/mg Bupivacaine hydrochloride.	Less than 1.8 USP EU/mg Bupivacaine hydrochloride.
7.	Sterility	Should be Sterile	Sterile
8.	Assay: Each ml contains: Bupivacaine Hydrochloride IP 5mg Dextrose Monohydrate IP 80mg	(4.65 mg to 5.35mg) 93.0% to 107.0% (74.4 mg to 85.6 mg) 93.0% to 107.0%	5.07 mg 101.4 % 81.74 mg 102.17 %

Remark: The sample is complies as per IP /BP/ USP/IH specification.

	Prepared By	Checked By	Approved By
Sign/Date	 07/09/2026	 07/09/2026	 07/09/2026
Name	Sanjana Negi	Manisha Thakur	Bhupinder Navet
Designation	Officer QC	Executive-QC	Head-QC

